Section 5
510(k) Summary

Name of Sponsor:	Ortho Development Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) Contact:	Tom Haueter Regulatory Affairs Manager Telephone: (801) 553-9991 Facsimile: (801) 553-9993 Email: thaueter@orthodevelopment.com
Date Prepared:	March 27, 2013
Trade Name:	Ovation 10/12 Hip Stem
Common Name:	Hip Stem Prosthesis
Classification:	21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Class II device
Device Product Code:	LPH
Predicate Devices:	Ovation® Hip Stem, *Ortho Development* (K062775) Taperloc® Hip Stem, *Biomet Orthopedics* (K043537) Anthology® Hip Stem, *Smith & Nephew* (K052792) Titanium Tri-Lock® Hip Stem, *DePuy Orthopedics* (K010367)

OCT 16 2013

5.1. Device Description:

The Ovation 10/12 Hip Stem is a one-piece press-fit tapered femoral stem, designed for single, uncemented use. The system consists of a variety of sizes to accommodate the majority of patients encountered, lengths (98-142mm), horizontal offsets (34-49mm), vertical offsets (29-36mm), resection angle of 130°, and neck angle of 132°.

The Ovation 10/12 Hip Stem has a rectangular cross-section and provides stability through a 3-point fixation. The femoral stem is manufactured from Titanium Alloy (ASTM F-136, Ti-6Al-4V ELI). The proximal portion of the stem is plasma-sprayed with titanium alloy (ASTM F-1580).

Section 5
510(k) Summary

5.2. Intended Use:

The Ovation 10/12 Hip Stem is intended for use in a total hip replacement surgery. Total hip arthroplasty is intended to provide increased patient mobility and to decrease pain by replacing the damaged hip joint in patients having sufficiently sound bone to support the implants.

5.3. Indications for Use:

The Ovation 10/12 Hip Stem is indicated for use in uncemented total hip arthroplasty procedures in cases of:

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed hip surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

5.4. Basis of Substantial Equivalence:

The Ovation 10/12 Hip Stem is substantially equivalent to the previously cleared predicate devices based on similarities in intended use, design, materials, manufacturing methods, packaging, and mechanical performance.

In accordance with ISO standards, proximal and distal fatigue tests were performed on the worst-case Ovation 10/12 Hip Stem to determine the stem's endurance performance. Further, a range of motion analysis was also performed. A summary of tests performed, results, and standards used is given below in Table 5.1.

Table 5.1: Testing Summary for Ovation 10/12 Hip Stem

ODEV Protocol/Report Number	ISO Standard(s)	Test Type	Test Specimen(s)	Test Results (Pass/Fail)
P-10-0017	ISO 7206-6:1992(E)	Proximal Fatigue	Size 1 Ovation 10/12 Hip Stem EXT (100-1001)	Pass
P-13-0065	ISO 7206-4:2010(E)	Distal Fatigue	Size 1 Ovation 10/12 Hip Stem EXT (100-1001)	Pass
R-13-0062A	ISO 21535:2007(E)	Range of Motion	Ovation 10/12 Hip Stem	Pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 16, 2013

Ortho Development Corporation
Mr. Tom Haueter
Regulatory Affairs Manager
12187 South Business Park Drive
Draper, Utah 84020

Re: K131022
Trade/Device Name: Ovation 10/12 Hip Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: September 3, 2013
Received: September 6, 2013

Dear Mr. Haueter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin FD Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use Statement

510(k) Number (if known): K131022

Device Name: Ovation 10/12 Hip Stem

Indications for Use:

The Ovation 10/12 Hip Stem is indicated for use in uncemented total hip arthroplasty procedures in cases of:

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed hip surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices